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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/021,818 | 12/13/2001 | Ronald W. Davis | 25436/1652 | 5874 |
| 27495 | 7590 | 04/20/2004 | EXAMINER | |
| PALMER & DODGE, LLP KATHLEEN M. WILLIAMS / STR 111 HUNTINGTON AVENUE BOSTON, MA 02199 | | | SULLIVAN, DANIEL M | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1636 | |

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/021,818

Applicant(s)

DAVIS ET AL.

Examiner

Daniel M Sullivan

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-37 is/are pending in the application.
- 4a) Of the above claim(s) 10-23 and 27-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-9 and 37 is/are rejected.
- 7) ☒ Claim(s) 24-26 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

This Non-Final Office Action is a reply to the Paper filed 26 January 2004 in response to the Non-Final Office Action mailed 8 August 2003. Claims 10-23 and 27-36 were withdrawn from consideration and claims 1-9 and 24-26 were considered in the 8 August Office Action. Claims 1 and 2 were canceled, claims 3, 4, 8, 9, 24 and 25 were amended and claim 37 was added in the 26 January Paper. Claims 3-37 are pending and claims 3-9, 24-26 and 37 are under consideration herein.

Response to Amendment

Objection to and rejection of claims 1 and 2 is rendered moot in view of cancellation thereof.

Claim Rejections - 35 USC § 112

Rejection of claim 24 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn in view of the amendments thereto.

Claim Rejections - 35 USC § 102

Claims 4-9 and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by von Arnim *et al.* (1998) *Gene* 221:35-43 for reasons of record and herein below in the response to arguments.

Rejection of claims 1-3 and 24 under 35 U.S.C. 102(b) as being anticipated by Wouters *et al.* (September 1999) *Curr. Biol.* 9:1127-1130, rejection of claims 1-3 and 25 under 35 U.S.C. 102(b) as being anticipated by Periasamy *et al.* (1997) *In Functional Imaging and Optical Manipulation of Living Cells*, Proc. SPIE 2983, ed. DL Farkas, BJ Tromberg. Bellingham, WA: SPIE and rejection of claim 1 under 35 U.S.C. 102(b) as being anticipated by Oker-Blom *et al.* (1996) *FEBS Lett.* 389:238-243 as evidenced by the NiceProt view of Swiss-Prot: P22629 is withdrawn. The art does not teach or suggest a recombinant fusion polypeptide comprising a first and second polypeptide wherein said first and second polypeptides are monomers of a multimeric fluorescent protein.

Response to Arguments and New Grounds for Rejection

Claim Rejections - 35 USC § 102

Claims 3-9 and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by von Arnim *et al.* (1998) *Gene* 221:35-43 as evidenced by Swiss-Prot Database Entry P42212.

In the previous Office Action, Claims 1 and 4-9 were rejected under 35 U.S.C. 102(b) as being anticipated by von Arnim *et al.* (1998) *Gene* 221:35-43. In response, Applicant has added new claim 37 which is directed to a recombinant fusion polypeptide limited to comprising a first polypeptide bonded to a second polypeptide via a linker sequence; and wherein the first and second polypeptides are monomers of a multimeric fluorescent protein, are not fluorescent donor and acceptor to each other and wherein the fusion polypeptide is fluorescent when excited.

Claims 4-9 have been amended to depend from claim 37. Applicant urges that, because von Arnim does not teach a linker sequence, the reference does not anticipate the claims.

This argument has been fully considered but is not deemed persuasive. Although the teachings of von Arnim were not previously applied to claims 2 and 3, which recite the linker limitation, it is clear upon further consideration of the “linker sequence” of the claims that the fusion protein of von Arnim comprises a “linker sequence” as that term is defined in the first paragraph on page 15 of the specification.

The specification states, “As used herein, the term ‘linker sequence’ refers to a sequence of peptide bonded amino acids that joins or links by peptide bonds two amino acid sequences or polypeptide domains that are not joined by peptide bonds in nature.” Given the broadest reasonable interpretation of this definition, any amino acid sequence that joins or links two amino acid sequences or domains that are not joined by peptide bonds in nature meets the limitation of a “linker sequence”. More to the point, the definition does not exclude the middle GFP moiety in the GFP trimer of von Arnim *et al.* or native GFP amino acid sequence from the meaning of “linker sequence”. Thus, the middle GFP moiety of the trimer or the amino acid sequence joining, for example, the fluorophore domains of the dimeric GFP read on a “linker sequence” and, therefore, the recombinant fusion polypeptide of von Arnim *et al.* reads on the instant claims 37 and 4-9 for reasons of record and herein.

With regard to claim 3, which limits the linker sequence to comprising from 5 to 50 amino acids, von Arnim *et al.* teaches a head to tail fusion resulting in a “linker sequence” between the “helix” at amino acids 4 to 8 to the “strand” at amino acids 217 to 227 (see the NiceProt view of Swiss-Prot: P42212). Thus, the fusion protein of von Arnim *et al.* comprises a linker sequence of 14 amino acids, which anticipates the limitations of claim 3.

The fusion protein of von Arnim *et al.* comprises all of the limitations of the instant claims; therefore, the claims are anticipated by von Arnim *et al.*

Allowable Subject Matter


Claims 24-26 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Thursday 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


ANNE-MARIE FALK, PH.D.
PRIMARY EXAMINER